OncoCyte Provides Corporate Update and Reports Second Quarter 2019 Financial Results

Aug 14, 2019

Molecular Diagnostics industry veteran Ron A. Andrews appointed CEO

Melinda Griffith elected to Board of Directors

Strengthened Clinical Operations and Commercial Marketing teams with key management appointments

Conference call today, August 14, at 4:30 PM EDT

ALAMEDA, Calif., Aug. 14, 2019 (GLOBE NEWSWIRE) -- OncoCyte Corporation (NYSE American: OCX), a developer of novel, non-invasive tests for the early detection of cancer, today reported financial and operating results for the second quarter ended June 30, 2019 and provided a corporate update.

“I am thrilled to have joined OncoCyte at such a pivotal time in the company’s evolution,” said Ron Andrews, Chief Executive Officer of OncoCyte. “As a member of the Board for over a year before taking my new role, I recognized the potential of OncoCyte’s immune interrogation approach and now as CEO, I can directly apply, on a day to day basis, the key learnings from my deep experience in molecular diagnostics to ensure we transition DetermaVu from the development phase to the clinical setting. Our current efforts are focused on ensuring we have a robust and reproducible test workflow for patient care, and since taking on the role of CEO in early July, we have identified and understand the critical variables that caused us to pause in mid-June.”

Mr. Andrews continued, “We have now clarified the key steps for our development path forward and our R&D team is diligently executing on the plan. We look forward to sharing more details on our conference call today. Importantly, concurrent to our work in the lab, we have also continued to advance our market preparation activities to create the commercial momentum necessary to move DetermaVu™ closer to market. This is just the beginning for OncoCyte, and with our solid balance sheet, I look forward to leading our outstanding team to deliver tests that improve clinical decisions throughout the patient journey in lung cancer and beyond.”

Highlights

- Appointed Ron A. Andrews as Chief Executive Officer, effective July 1, 2019. Mr. Andrews brings over 30 years of extensive experience in the clinical and molecular diagnostics field, including serving as President of Life Technologies’ Medical Sciences Venture and the Genetic Sciences Division of Thermo Fisher Scientific, and Chief Executive Officer of Clarient, Inc., which was acquired by GE Healthcare, along with senior management roles at Roche Molecular Diagnostics, Immucor Inc., and Abbott Diagnostics.

- Appointed Melinda Griffith to Board of Directors as an independent board member. Ms. Griffith currently serves as Vice President of Strategic Alliances and Chief Legal Counsel at the Parker Institute for Cancer Immunotherapy and brings extensive business development and legal experience in advising public and private companies in the diagnostics and life sciences sectors.
- Appointed Padma Sundar as Senior Vice President of Marketing and Market Access. Ms. Sundar brings significant experience in preparing and developing markets for molecular diagnostic tests, with a focus on the liquid biopsy field. She also has relevant experience in commercializing and driving adoption of novel, high value tests, from her experience at companies such as Guardant Health, Roche Sequencing and Affymetrix.
- Appointed Dr. Kim Dickinson as Vice President of Clinical Operations to help advance OncoCyte's R&D programs and clinical studies. Dr. Dickinson is an experienced leader in clinical operations and pathology with proven expertise in overseeing global clinical trials and diagnostic testing, with an emphasis on anatomic, clinical and digital pathology. Dr. Dickinson gained her relevant experience at global leaders such as Roche Tissue Diagnostics and Lab Corp where she held senior positions in R&D and Clinical Trial Operations and also served as Medical Director for their clinical trial initiatives.
- Appointed Tony Kalajian, CPA, MBA as Senior Vice President, Chief Accounting Officer. Mr. Kalajian brings over 20 years of experience in domestic and international financial reporting, auditing and accounting, with prior roles at BioTime Inc., STAAR Surgical Company and PricewaterhouseCoopers.

Second Quarter 2019 Financial Highlights

At June 30, 2019, OncoCyte had cash, cash equivalents, and marketable securities of $36.3 million as compared to $8.5 million at December 31, 2018. The balance sheet was strengthened in February 2019 with the successful equity raise of $37.0 million in net proceeds from an underwritten public offering.

For the second quarter ended June 30, 2019, OncoCyte incurred a net loss of $ 5.4 million, or $(0.10) per share, as compared to $4.5 million, or $(0.12) per share, for the three months ended June 30, 2018.

Operating expenses, as reported, for the three months ended June 30, 2019 were $5.5 million, an increase of $1.2 million as compared to the same period in 2018. Operating expenses, as adjusted, for the three months ended June 30, 2019, were $4.3 million, an increase of $1.3 million as compared to the same period in 2018.

The reconciliation between operating expenses determined in accordance with accounting principles generally accepted in United States (GAAP) and operating expenses, as adjusted, a non-GAAP measure, is provided in the financial tables included at the end of this press release.

Research and development expenses for the quarter ended June 30, 2019 were $1.5 million as compared to $2.3 million for the same period in 2018, a decrease of $0.8 million. This decrease was primarily due to a decrease in $0.7 million in amortization expense of intangible assets, reflecting a $0.6 million noncash impairment charge recorded as of June 30, 2018 related to intangible assets mainly comprised of patents and patent rights for therapeutic uses that OncoCyte no longer plans to develop or commercialize. There was no amortization expense recorded for the three months ended June 30, 2019.

General and administrative expenses for the three months ended June 30, 2019 were $3.6 million, as compared to $1.3 million for the same period in 2018, an increase of $2.3 million. This increase is primarily attributable to investment banking related expenses; personnel and related expenses, including management transition costs; legal, recruiting, accounting, audit and tax services expenses; stock-based compensation expense due to additional equity grants, including to new hires; financial advisory expenses; and expenses of meetings, conferences and seminars.

Sales and marketing expenses for the three months ended June, 2019 were $0.3 million, as compared to $0.6 million for the same period in 2018, a decrease of $0.3 million. Although OncoCyte reduced its sales and marketing related expenses during the periods reported, in late May 2019, OncoCyte hired a Senior Vice President of Marketing and Market Access, and expects that sales and marketing expenses will increase as it continues to build a sales and marketing team, at the appropriate time, for the planned commercialization of DetermaVu.

Cash used in operations was $2.8 million for this quarter as compared to approximately $4.0 million during the second quarter in 2018, in line with OncoCyte's expectations for the current quarter's cash burn of around $1 million per month.

Conference Call

The Company will host a conference call today, August 14, 2019, at 4:30 pm EDT / 1:30 pm PDT to discuss the results along with recent corporate developments.

The dial-in number in the U.S./Canada is 877-407-9716; for international participants, the number is 201-493-6779. For all callers, please refer to Conference ID 13692586. To access the live webcast, go to the investor relations section on the Company's website, http://public.viavid.com/index.php?id=135362.

About OncoCyte Corporation

OncoCyte is focused on the development and commercialization of novel, diagnostic tests for the early detection and management of cancer, when it is most curable. OncoCyte has developed a proprietary liquid biopsy that can assess the immune system's response to cancer at its earliest stages. The first application of this liquid biopsy is a blood test in development to aid in the diagnosis of lung cancer and reduce the need for risky and costly diagnostic procedures such as invasive lung biopsies.

OncoCyte Forward Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates" and similar expressions) are forward-looking statements. These statements include those pertaining to the time to complete and the results of the Company's ongoing CLIA Validation study, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for OncoCyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of OncoCyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in OncoCyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. OncoCyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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ONCOCYTE CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 35,826	$ 8,034
Marketable equity securities	518	428
Prepaid expenses and other current assets	720	180
Total current assets	37,064	8,642
NONCURRENT ASSETS		
Machinery and equipment, net	413	614
Deposits and other noncurrent assets	189	262
TOTAL ASSETS	$ 37,666	$ 9,518

LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$ 5	$ 2,101
Accounts payable	556	166
Accrued expenses and other current liabilities	2,486	2,109
Loan payable, current, net of deferred financing costs	769	800
Financing lease liability, current	245	385
Total current liabilities	4,061	5,561
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	-	347
Financing lease liability, noncurrent	100	187
TOTAL LIABILITIES	4,161	6,095
SHAREHOLDERS’ EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 51,973 and 40,664 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	114,071	74,742
Accumulated other comprehensive loss	-	-
Accumulated deficit	(80,566)	(71,319)
Total shareholders' equity	33,505	3,423
TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY	$ 37,666	$ 9,518

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
EXPENSES:				
Research and development	$ 1,508	$ 2,322	$ 2,851	$ 3,784
General and administrative	3,636	1,335	6,085	3,122
Sales and marketing	318	569	523	1,227
Total operating expenses	5,462	4,226	9,459	8,133
Loss from operations	(5,462)	(4,226)	(9,459)	(8,133)
OTHER INCOME (EXPENSES), NET				
Interest income (expense), net	167	(56)	147	(117)
Unrealized gain (loss) on marketable equity securities	(88)	(223)	90	(32)

Other expenses, net	-	-	(25)	(2)
Total other income (expenses), net	79	(279)	212	(151)
NET LOSS	$ (5,383)	$ (4,505)	$ (9,247)	$ (8,284)
Net loss per share: basic and diluted	$ (0.10)	$ (0.12)	$ (0.19)	$ (0.24)
Weighted average common shares outstanding: basic and diluted	51,973	38,708	49,324	35,211

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	Six Months Ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,247)	$ (8,284)
Adjustments to reconcile net loss to net cash used in operating activities:		

Depreciation expense	194	207
Amortization of intangible assets	-	121
Amortization of prepaid maintenance	18	-
Impairment charge for intangible assets	-	625
Stock-based compensation	1,388	735
Unrealized (gain) loss on marketable equity securities	(90)	32
Amortization of debt issuance costs	22	44
Other	26	22
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	(2,096)	1
Prepaid expenses and other current assets	(540)	(214)
Accounts payable and accrued liabilities	767	1
Net cash used in operating activities	(9,558)	(6,710)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of equipment	(18)	(22)
Security deposit and other	54	-
Net cash provided by (used in) investing activities	36	(22)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	943	56
Proceeds from sale of common shares	40,250	10,000
Financing costs to issue common shares	(3,252)	(65)
Repayment of loan payable	(400)	(400)
Repayment of financing lease obligations	(227)	(165)

Net cash provided by financing activities	37,314	9,426
NET INCREASE IN CASH AND CASH EQUIVALENTS	27,792	2,694
CASH AND CASH EQUIVALENTS:		
At beginning of the period	8,034	7,600
At end of the period	$ 35,826	$ 10,294

Non-GAAP Financial Measures

This earnings release includes operating expenses prepared in accordance with accounting principles generally accepted in the United States (GAAP), and includes certain historical non-GAAP operating expenses. In particular, OncoCyte has provided non-GAAP total operating expenses, adjusted to exclude noncash stock-based compensation, depreciation and amortization, an impairment charge for intangible assets, and certain warrants expense. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable financial measures prepared in accordance with GAAP. However, OncoCyte believes the presentation of non-GAAP total operating expenses, when viewed in conjunction with our GAAP total operating expenses, is helpful in understanding OncoCyte's ongoing operating expenses and its programs.

Furthermore, management uses these non-GAAP financial measures in the aggregate to establish budgets and operational goals, to manage OncoCyte's business and to evaluate its performance and its programs.

OncoCyte Corporation

Reconciliation of Non-GAAP
Financial Measure

Adjusted Operating Expenses

	Amounts In Thousands	**Amounts In Thousands**

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
GAAP Operating Expenses - as reported	**$ 5,462**	**$ 4,226**	**$ 9,459**	**$ 8,133**
Stock-based compensation expense	(701)	(389)	(1,388)	(735)
Impairment charge for intangible assets	-	(625)	-	(625)
Noncash warrant expense	(329)	-	(329)	-
Depreciation and amortization expense	(84)	(164)	(194)	(328)
Non-GAAP Operating Expenses, as adjusted	$ 4,348	$ 3,048	$ 7,548	$ 6,445



Source: OncoCyte Corporation

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